

application as is common in the literature reporting on the preparation of monoclonal antibodies. Being his own lexicographer, Applicant has accompanied the designated name "mAb 1D9" by a definition of properties that would be precise and definite enough for the ordinary artisan to recognize the monoclonal antibody encompassed by the claims.

Furthermore, Figure 1 displays a photograph of a Western immunoblot analysis of the monoclonal antibody, mAb 1D9, which is identified as specific for the epitope of the inactivated FIV-encoded glycoprotein. Additional Western immunoblot analyses can readily distinguish antibodies and identify mAb 1D9 as indicated by the broad 95-100 Kd band. Because monoclonal antibodies are identical, once the monoclonal antibodies that specifically bind to a given substance such as the epitope of the inactivated FIV-encoded glycoprotein have been produced, they can then serve to detect the presence and quantity of the substance, for instance, in the Western blot test (to detect a protein on a membrane) or an immunofluorescence test (to detect a substance in a cell). In this case, the mAb 1D9 will recognize the surface protein of the inactivated FIV but not that of live FIV and possess the same inherent properties as the monoclonal antibody of Claim 1. The functional and novel selectivity in the binding properties of the monoclonal antibody produced by the repeatable methods taught in the application in which the monoclonal antibody is screened for specific reactivity with inactivated FIV provides adequate guidance to allow identification of the product known as "mAb 1D9" embraced by Claims 7 and 21.

In essence, Claim 1 is drawn to the monoclonal antibodies in general terms of the specific antigenic determinant or epitope with which it reacts, that is, defined in terms of its binding characteristics to the epitope of the inactivated FIV-encoded glycoprotein but not to live FIV or live FIV glycoprotein. Claims 7 and 21 define the monoclonal antibody specifically and more narrowly to be the designated mAb 1D9 or the hybridoma cell line for obtaining mAb 1D9 that resulted from the experimental data of the working examples using inactivated FIV-Shizuoka to produce the monoclonal antibodies. It is plain to see that the ordinary practitioner would know what is intended by "mAb 1D9" recited in the claims.

In view of the amendment and the foregoing comments, Applicant respectfully requests that the rejection of Claims 1-10 and 19-21 under 35 U.S.C. § 112, second paragraph, be withdrawn.

The Examiner also rejects Claims 1-6, 8-10 and 19-20 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement for reasons given on pages 4-7 of the Office action. Applicant respectfully traverses the rejection.

It is submitted that the written description adequately teaches the present invention to one of ordinary skill in the art. On page 4, lines 5-12, the general method that can be used to produce and screen for the monoclonal antibody is disclosed. Working Example 1 describes in more detail how to generate the monoclonal antibody of the invention using formalin-treated FIV-Shiz virus as a representative antigen selected from the several antigen stocks that are prepared from a variety of other FIV strains and identified on page 6, lines 1-15. One of ordinary skill in the art would learn from the example that any of those numerous, known starting materials could be readily substituted for the illustrated formalin-treated FIV-Shiz virus to obtain the monoclonal antibody specific for the inactivated FIV-encoded glycoprotein.

On page 4, lines 14-15, an alternative method to obtain the monoclonal antibody of the invention is described in which the monoclonal antibody may be produced by a cell line deposited with the American Type Culture Collection and assigned the number ATCC number PTA-4837. Since monoclonal antibodies are identical, there is no reason for Applicant to describe additional species comprising the genus of monoclonal antibodies having the specific binding characteristics recited in the claims.

In terms of use, the assay for the determination of the quantity of an inactivated virus or for the potency of an inactivated FIV vaccine is described generally on page 4, lines 24-28 and in more detail in the working Examples 2 and 3 that show how to use the monoclonal antibody as a detection antibody in ELISA and immunoprecipitation techniques. Table 1 of Example 4 on page 9 demonstrates the specificity of the monoclonal antibody in selectively reacting with the inactivated FIV-Shiz and FIV-Petaluma viruses but not live FIV-Shiz and FIV-Petaluma viruses, nor any of the other inactivated or live antigens, such as the feline leukemia virus (FeLV), feline calicivirus (FCV), feline viral rhinotracheitis virus (FVR) and feline panleukopenia virus (FPV). There is no question that Applicant was in possession of the claimed invention when the application was filed in the U.S. Patent and Trademark Office.

In view of the foregoing remarks and the evidence, Applicant respectfully asks that the rejection of Claims 1-6, 8-10 and 19-20 under 35 U.S.C. § 112, first paragraph, be withdrawn.

The Examiner further rejects Claims 1-10 and 19-22 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement for reasons set forth on pages 7-10 of the Office action.

It is assumed that the Examiner's inclusion of the allowable Claim 22 in this rejection is an inadvertent error. Correction of the record is respectfully requested.

Additionally, this rejection, which is based on the deposit of the biological material designated mAb 1D9, had been fully addressed earlier in the prosecution history of this application. The Examiner's attention is respectfully drawn to the Amendment filed on September 12, 2005 in which the specification was amended to add the date of deposit, the full address of the ATCC depository and the point that the deposit was made under the Budapest Treaty; the comments on page 5 of the response included the averments about the public availability of the deposit as required by statute; and, finally, a copy of the deposit receipt from the ATCC was supplied for the Official records.

In sum, the rejection of Claims 1-10 and 19-21 under 35 U.S.C. § 112, first paragraph, appears to be unwarranted and should be removed as it now stands.

The Examiner rejects Claims 19-21 under 35 U.S.C. § 102(b) as being allegedly anticipated by O'Connor *et al.* (U.S. Patent No. 5,177,014) for reasons given on pages 10 and 11 of the Office action.

Considering the Examiner's helpful comments, it is believed that the Office recognizes the novelty of the monoclonal antibody of the present invention that is specific for inactivated FIV and forms a strong interaction with an epitope unique to an inactivated FIV envelope glycoprotein, to the exclusion and non-recognition of live FIV. Therefore, without comment as to the merits of the rejection based on O'Connor *et al.* but to expedite matters, Claim 19 has been rewritten for the better readability thereof. As amended, the claimed subject matter requires that the hybridoma cell line being screened for specific reactivity with inactivated FIV has no reaction with or recognition of live FIV.

In view of the amendment, Applicant respectfully asks that the rejection of Claims 19-21 under 35 U.S.C. § 102(b) be withdrawn.

Applicant gratefully acknowledges that the Examiner has deemed Claim 22 allowable. It is additionally noted that while product Claims 1-10 and 19-22 are under examination,

Applicant has amended the withdrawn method Claims 11-18 to require all of the limitations included in the product claims in order to preserve the right to rejoinder when the product claims are allowed. If any outstanding issue remains, the Examiner is invited to contact the undersigned attorney for a discussion of mutually agreeable solutions.

Accordingly, this application is now in condition for an allowance. Such favorable treatment is respectfully urged.

Respectfully submitted,

WYETH

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By: Anne M. Rosenblum

Anne M. Rosenblum

Attorney for Applicant

Registration No. 30,419

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Anne M. Rosenblum

Anne M. Rosenblum